

### **REMARKS**

Claims 1-10 are pending in the present application. Claims 1 and 3-7 have been amended. Claims 8-10 have been newly added.

Claim 1 has been amended to limit the amount of l-menthol and polyethylene glycol, both of which are the residual irritation reducing agent, and to add the word "residual" for the irritation reducing agent. Claim 2 has been amended to have a proper Markush type claim language. Claims 3 has been amended to be dependent on claim 1 only and to delete both the amounts of l-menthol and polyethylene glycol, which is broader than those in claim 1 as amended. Claims 4-7 have been amended to be dependent on claim 1 only. Support for these amendment can be found throughout the specification and the claims as originally filed, for example, paragraph [0006] for the term "residual", paragraph [0020] for the amount 0.5-1.5 mass% of l-menthol, and paragraphs [0024] and [0079] (Example 1) for the amount 10-25 mass% of polyethylene glycol.

Claims 8-10 have been newly added to further limit claim 2 with respect to the water vapor transmission of the support (claim 8) and the amount of the warming material (claim 9), and to further comprise a non-steroidal anti-inflammatory drug. Support for these newly added claims can be found throughout the specification as originally filed, in particular, original claims 3-5.

The amendments to the claims and the addition of claims are solely to advance prosecution. Applicants, by amending any claims herein, make no admission as to the

validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert the original claim scope of any claim amended herein, in a continuing application.

Amended claim 1 recites "A warming patch, comprising: a support; and an adhesive layer disposed on at least one surface of said support, the adhesive layer comprising a warming material, l-menthol, and polyethylene glycol as a residual irritation reducing agent, and the amount of said l-menthol and said polyethylene glycol are respectively 0.5-1.5 mass% and 10-25 mass%, based on the total amount of said adhesive layer."

No new matter has been introduced to this application within the meaning of 35 U.S.C. §132.

In view of the following, further and favorable consideration is respectfully requested.

***I. At page 2 of the Official Action, claims 4-7 have been objected to under 37 CFR 1.75(c) as being in improper form of dependent claims.***

In this regard, Applicants submit that presently pending claims 4-7, as amended, recite claim 1 only. Accordingly, withdrawal of this objection is respectfully requested.

***II. At page 3 of the Official Action, claims 1-3 have been rejected under 35 USC § 102(b) as being anticipated by MANABE (JP 2002-029993).***

The Examiner asserts that claims 1-3 are anticipated by Manabe since in the examples, Manabe teaches warming patches comprising 0.01% hot pepper extract, as a warming substance, and 0.25% l-menthol and 4.0% polyethylene glycol, as water

soluble adhesive polymers, in an adhesive base composition spread on a support.

Applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

In the present application, independent claim 1, as amended, recites “A warming patch, comprising: a support; and an adhesive layer disposed on at least one surface of said support, the adhesive layer comprising a warming material, l-menthol, and polyethylene glycol as a residual irritation reducing agent, and the amount of said l-menthol and said polyethylene glycol are respectively 0.5-1.5 mass% and 10-25 mass%, based on the total amount of said adhesive layer.” That is, the presently claimed warming patch comprises specifically narrowed amount of l-menthol, i.e., **0.5-1.5 mass% of l-menthol**, and polyethylene glycol i.e., **10-25 mass% of polyethylene glycol**. These specific amounts for l-menthol and polyethylene glycol are **critical** to the general function of the claimed invention.

However, Manabe does **not teach** the specific amount of l-menthol, nor the specific amount of polyethylene glycol. All the examples of Manabe describe only the use of 0.25% of l-menthol and the use of 0.4% polyethylene glycol. Nowhere does

Manabe specifically describe the specifically claimed amount of l-menthol and polyethylene glycol. Accordingly, Manabe fails to teach each and every elements of claim 1, as required by *Verdagaal Bros. v. Union Oil Co. of California*.

Further, Manabe only teaches that polyethylene glycol can be blended **as a moisture-retainer**. See Manabe, paragraph [0017]. Nowhere does Manabe teach the use of polyethylene glycol as a residual irritation reducing agent. Accordingly, a person of ordinary skill in the art reading the disclosure of Manabe, would not have considered using polyethylene glycol as a residual irritation reducing agent. In this context, Manabe fails to teach each and every element as “arranged in the same way as in the present claims,” as required by *In re Bond*.

As such, Manabe does not anticipate present claims 1-3. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

**III. At page 4 of the Official Action, claims 1-3 have been rejected under 35 USC § 103(a) as being obvious over lida (JP 1991-161435).**

The Examiner asserts that lida teaches components of 0.2% capsicum extract, 0.5-1.0% l-menthol and 1.0-10% polyethylene oxide. The Examiner additionally asserts that although lida does not teach a composition combining each of the components, and also does not teach capsicum extract in the percent range as claimed, a skilled artisan would have found the present claims obvious in view of lida.

Applicants respectfully traverse this rejection. To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court recently held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), “a

court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ... it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ 1016, 1023 (C.C.P.A 1970). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

lida describes a patch that suppresses skin irritation, which comprises l-menthol, or comprises capsicum extract, or comprises l-menthol and polyethylene glycol. However, ***no patches comprising all of a warming material, l-menthol and propylene glycol is described or suggested by lida.***

In this regard, the Examiner asserts that “if an artisan wanted to make a patch of lida’s Example 10 (Table 6) having warming qualities, one would be motivated to add capsicum extract to the patch composition as taught by lida, thus providing a warming composition as known in the art.”

Applicants, however, do not agree with the Examiner on this point. As described in the present application, see paragraph [0004], capsicum extract is a warming material,

while l-menthol is a cooling agent. The functions of the two materials are completely opposite to each other. A skilled artisan, reading the disclosure of lida, would not have been motivated to add capsicum extract to a composition which comprises considerable amount of l-menthol, where the skilled artisan wanted to make a warming patch. lida's Example 5, which comprises capsicum extract but does not comprise l-menthol evidences this.

Furthermore, it should be noted that the skin irritation as described in lida is absolutely different from the residual irritation recited in the present claims. Specifically, the skin irritation in lida refers to ***itchiness and skin eruptions*** which resulted from ***the suppression of evaporation and dispersion of the moisture*** in the ointment. See English translation of lida, first paragraph of page 3. lida proposes a patch where the moisture permeability of a support is 100-4000 g/m<sup>2</sup>/24h, in order to solve the problem. In contrast, the residual irritation in the present claims refers to ***residual irritation after peeling the patch off, particularly the prickling feeling by elevating body temperature due to bathing, etc.*** See the present application, paragraphs [0024] and [0085] to [0088]. Obviously, the residual irritation in the present claims does not relate to the evaporation and dispersion of the moisture in the patch, as described in lida. It is well known in the art that capsaicin is an agonist of TRPV1, which is a heat activated calcium channel, explaining why capsaicin is linked to the sensation of heat. It is also well known in the art that irritation from capsaicin, such as sensations of heat and pain, remains in the skin even after the patch comprising such warming materials, is peeled

off from the skin. Accordingly, the skin irritation as described in lida is absolutely different from the skin irritation described in the present claims.

In view of the above, there is no reason that would have prompted a skilled artisan to combine and arrange the components in the same way as the present claims do, as required by *KSR International Co. v. Teleflex Inc.* Nothing in lida renders the present claims obvious under the meaning of 35 USC § 103(a).

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

**IV. At page 4 of the Official Action, claims 1-3 have been rejected under 35 USC § 103(a) as being obvious over Mori (JP 1981-010888), in view of Weiss (US 3,944,663) and Okamoto (JP 06-256183).**

The Examiner asserts that the present claims are obvious from the combination of Mori, Weiss and Okamoto since Mori teaches patch compositions with low skin irritation containing capsicum extract and l-menthol and further teaches the use of 10-70% polyethylene glycol, and in view of Weiss and Okamoto, selecting polyethylene glycol and optimizing the percent ranges for each component would have been obvious.

Applicants respectfully traverse this rejection. Again, to establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court recently held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), “a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ... it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field

to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ 1016, 1023 (C.C.P.A. 1970). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Mori describes a heat stimulating patch with suppressed “skin irritation (rash; in Japanese “かぶれ”).” The cause of the “skin irritation” is described as a result of the failure of sweat absorption (lines 9 to 14, page 2, translation of Mori), and the problem is solved by using a water base agent, instead of a conventional oily type. However, Mori fails to point out the residual irritation of a heat stimulating patch as recited in the present claims, and therefore does not suggest any resolution of residual irritation reduction.

Further, Mori describes a patch comprising capsicum extract and a polyatomic alcohol, and teaches that l-menthol may be blended as an essential oil constituent, and polyethylene glycol is an example of polyatomic alcohols. Mori further describes that “a polyatomic alcohol retains the moisture performance of the base agent for a long period of time and extends the effects.” See, English translation of Mori, lines 2-4 of page 3.



Accordingly, Mori teaches that polyatomic alcohols acts as a moisturizing agent. However, Mori does not teach the fact that polyethylene glycol may reduce the residual irritation from a heat stimulating patch. ***Nowhere does Mori teach or suggest the use of polyethylene glycol for reducing the residual irritation from a heat stimulating patch.*** Accordingly, Mori does not describes all of the elements of the present claims, as required by *In re Wilson*.

In this regard, the Examiner asserts that “the skin irritation reducing properties of polyethylene glycol were recognized decades ago. As evidenced, Weiss teaches that homopolymers of ethylene oxide, i.e., polyethylene glycol, for example, in concentration up to 5% by weight, act to reduce skin irritation ... Furthermore, Okamoto disclose the use of polyethylene glycols as an irritation-reducing agent in a patch containing l-menthol and irritation inducing NSAID (abstract).” Applicants do not agree with the Examiner on this point. Weiss describes a mild light duty detergent. Weiss suggests that homopolymer of ethylene oxide, namely polyethylene glycol, may reduce the skin irritation, which is described as “***reddening or chapping of the affected area or in extreme cases, actual cracking of the skin.***” See Weiss, Col. 1, lines 24-26. Accordingly, Weiss cannot remedy the deficiencies of Mori.

Okamoto describes an antiphlogistic analgesic patch. Okamoto further teaches that polyoxyalkylene glycol is blended as an irritation reducing agent. However, similar to Weiss, the “irritation” means “erythema” in Okamoto. See the Japanese specification of Okamoto, paragraph [0002]. Further, Okamoto describes that although the level of

“irritation” varies depending on the compositions, the “irritation” is almost unpreventable whether or not an active ingredient exists and whatever the active ingredient is. Accordingly, it is clear that Okamoto does not teach or suggest the residual irritation in a warming patch, and does not teach or suggest that polyoxyalkylene glycol may be used as a residual irritation reducing agent in a warming patch. Accordingly, Okamoto, taken alone or in combination with Weiss cannot remedy the deficiencies of Mori.

As such, Mori, Weiss and Okamoto, taken alone or in combination, do not teach or suggest the present claims. Nothing in the Mori, Weiss and Okamoto references, taken alone or in combination, renders the present claims obvious under the meaning of 35 USC §103. Thus, reconsideration and withdrawal of this rejection of present claims 1-3 is respectfully requested.

**CONCLUSION**

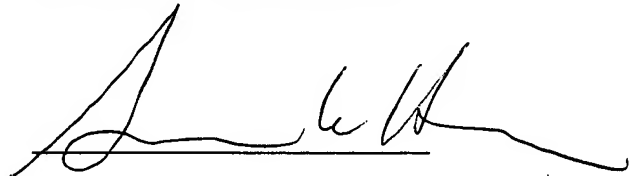
In view of the foregoing, Applicants submit that the pending claims are in condition for allowance. Early notice to this effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed such contact will expedite the prosecution of the application.

If the Examiner has any questions or comments regarding this matter, he is welcomed to contact the undersigned attorney at the below-listed number and address.

In the event this paper is not timely filed, applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

**THE NATH LAW GROUP**

A handwritten signature in black ink, appearing to read 'Gary M. Nath', is written over a horizontal line.

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